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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,430	12/26/2006	Christopher Hug	SER-100X	3770
23557 7590 12/08/2009 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO Box 142950 GAINESVILLE, FL 32614				
EXAMINER DUTT, ADITI				
ART UNIT		PAPER NUMBER		
1649				
NOTIFICATION DATE		DELIVERY MODE		
12/08/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

euspto@slspatents.com

### Office Action Summary

**Application No.**

10/553,430

**Applicant(s)**

HUG ET AL.

**Examiner**

Aditi Dutt

**Art Unit**

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 71-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 71-75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Claims***

1. The amendments filed on 24 August 2009 have been entered into the record and have been fully considered. Claims 1-70 have been cancelled. New claims 71-75 have been added.
2. Claims 71-75, drawn to a method of treating obesity comprising administration of a composition comprising a soluble T-cadherin polypeptide to an obese individual, are under consideration in the instant application.

### ***Response to Amendment***

#### Withdrawn objections and/or rejections

3. Upon consideration of the Applicant's amendment, all claim objections and rejections, not reiterated herein have been withdrawn, as overcome by cancellation and/or amendment of claims (24 August 2009).
4. The rejection of claims 68 and 70 under 35 U.S.C. 112, second paragraph is withdrawn, because of cancellation of claims and Applicant's persuasive argument.
5. The rejection of claims 59-62 and 66-70, under 35 U.S.C. 112, first paragraph, written description is withdrawn, because of cancellation of the broad claims and limiting the independent claim.

6. The rejection of claims 59, 60 and 62 under 35 U.S.C. 102(e) is withdrawn, because of cancellation of the broad claims, and because the prior art reference does not teach soluble T-cadherin.
7. The rejection of claims 59, 61 under 35 U.S.C. 103(a) is withdrawn, because of cancellation of claims reading on combination treatment.

***Response to Amendment***  
**Rejections Maintained**

**35 USC § 112-Scope of Enablement**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. The rejection of claims 59-62, 66-70 under 35 U.S.C. 112, first paragraph, scope of enablement is applied to the new claims 71-75, for reasons of record in the Office Action dated 23 February 2009.
9. Asserting that the claims are enabled, Applicant argues that the Office Action has not presented any evidence that soluble T-cadherin or cadherin molecules that lack a GPI anchor will not bind Acrp30 or adiponectin. Applicant further states that the current claim amendment removing the limitations directed to "any fragment, variant or mutant of T-cadherin" renders the enablement

rejection based on the same as moot. Applicant therefore, requests the withdrawal of the rejection.

10. Applicant's arguments are fully considered, however, are persuasive in part. Applicant's claim amendments limiting to a soluble T-cadherin represented by specific sequences have resulted in the withdrawal of enablement issues pertaining to an indefinite number of unidentified fragments or variants of T-cadherin. However, the instant specification while being enabling for treating obesity by administration of a composition comprising a full-length T-cadherin polypeptide having the glycosylphosphatidylinositol (GPI) anchor domain intact, does not still reasonably provide enablement for a method of treating obesity by administering a soluble T-cadherin polypeptide having the GPI site mutated or deleted for reasons stated in the previous Office Action.
11. Firstly the instant specification teaches that full-length T-cadherin binds to hexameric and HMW species of Arcp30 in mammalian cells (Example 4); and that T-cadherin over-expression suppresses the Arcp30 induced NF-kB mediated transcription (Example 5, Figure 4). The specification neither provides a working example demonstrating any criticality of the soluble form of T-cadherin, nor suggests any indication or sound scientific reasoning, that would translate the results of using full-length T-cadherin to soluble T-cadherin molecules. Moreover, the relevant literature does not provide any guidance to the skilled artisan in this regard. On the contrary, the art teaches that the mature protein molecule attaches to cell surface by way of the GPI anchor domain that allows signal

transduction and initiate important signaling pathways (Kipmen-Korgun et al. J Cardio Pharm 45: 418-430, 2005; page 428, col 1, para 2). As stated in the previous Office Action, it is reiterated that only membrane bound T-cadherin binds lipoproteins in mammalian cells, while T-cadherin cleaved from the cell surface by GPI specific phospholipase, or T-cadherin lacking the GPI signal sequence do not bind to the low density lipoproteins (LDL). The art also teaches that T-cadherin is a receptor for both adiponectin and lipoprotein (Kipmen-Korgun et al. page 418, col 2, para2). Because the signaling pathway is required for physiological function, and because lipoprotein is an important protein involved in metabolic functions that have been established to be mediated through signal transduction via binding to GPI-anchored T-cadherin, it would be reasonable for a skilled artisan to deduce that the making and using of a soluble T-cadherin devoid of the GPI-anchor site for the treating of obesity would be unpredictable. The skilled person of art would be further confounded by the absolute lack of any guidance or sound scientific reasoning for the use of soluble T-cadherin, either in the instant specification or in the relevant literature. Lastly, the claims do not recite binding of soluble cadherin to adiponectin, i.e. the claims do not require any particular mechanism of action for treating obesity. It is noted that Applicant is arguing specific and narrow mechanistic features not presented in the instant claims. MPEP 2164.08(c) states that "A feature which is taught as critical in a specification and is not recited in the claims should result in a rejection of such

claim under the enablement provision section of 35 U.S.C. 112. See *In re Mayhew*, 527 F.2d 1229, 1233, 188 USPQ 356, 358 (CCPA 1976)".

12. Specifically, a proper analysis of the Wands factors was provided in the previous Office Action. Due to the large quantity of experimentation necessary to treat metabolic disorders such as obesity by administering a soluble form of T-cadherin polypeptide lacking GPI anchor site or having a mutated GPI site; the absolute lack of direction/guidance presented in the specification regarding the same; the complex nature of the invention; the unpredictability of a desirable therapeutic effect of a soluble T-cadherin polypeptide on obesity or any metabolic disorder - undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

***New Objection/Rejection***

***Claim Objection***

13. Claim 71 is objected for the following informalities:
- Claim 71 has a typo on lines 1 and 2. The phrase "comprising the administration of a composition" is repeated.
- Appropriate correction is required.

***Claim Rejections - 35 USC § 112-Second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 71-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
15. Claim 71 is rejected for reciting the phrase "an obesity" that is vague and unclear. It is not ascertainable as to how many types of obesity exist, or are being encompassed by the phrase.
16. Claim 72 is rejected for depending from a rejected claim.

***Conclusion***

17. No claims are allowed.
18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
19. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will



the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is (571) 272-9037. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:00 p.m.
21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AD  
20 November 2009

/Jeffrey Stucker/

Supervisory Patent Examiner, Art Unit 1649